



# STATE OF CONNECTICUT

DEPARTMENT OF SOCIAL SERVICES

25 SIGOURNEY STREET • HARTFORD, CONNECTICUT 06106-5033

May 30, 2002

11 83 '02 JUN -7 A9:29

Dockets Management Branch (HFA-305)  
Food and Drug Administration, Rm. 1061  
5630 Fishers Lane  
Rockville, MD 20857

Re: Docket No. 91N-384H  
96P-0500

To Whom It May Concern:

I recommend that the stay of the second-tier sodium level requirements be until January 1, 2004, rather than January 1, 2006 as proposed, if and only if FDA is considering a more restrictive sodium requirement. Otherwise, the January 1, 2003 deadline should be enforced. These are my reasons:

1. To justify the decision to further stay implementing the second tier sodium provisions beyond January 1, 2003, the notice contains two misleading statements. These are:
  - a. "To comply with this effective date, manufacturers would have to reformulate and/or re-label their products within a short timeframe." In fact, manufacturers have had since May 10, 1994 when the final rule defining the term "healthy" was published, **9 years!!!???**
  - b. "FDA has determined that it is in the public interest to issue this [stay]..." The "public interest" stated in the notice cannot be the general public, who would be put at further risk by the delay. It must therefore refer only to a few vocal or influential manufacturers.
2. The higher sodium values are not "healthy" in the furthest stretch of the imagination. The tendency to keep extending second-tier sodium requirements smacks of industry favoritism rather than a concern for the health of America's citizens.
3. Even the second-tier sodium levels are too high. The recommended upper sodium limit for Americans is 2400 milligrams for an 1800 - 2700 kilocalorie diet, or about 1 milligram per kilocalorie. Any food that provides a disproportionate amount of sodium for its energy content should not be considered "healthy."

91N-384H

C 124

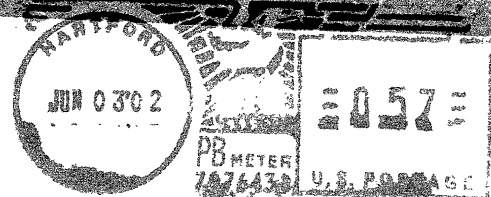
4. Thirty percent of older adults have hypertension and half of these are sodium responders. FDA is toying with a regulation that addresses a sizable proportion of the population and impacts a significant health problem, partly correctable through diet.
5. Failure to enforce truth-in-labeling is to abrogate responsibility. Manufacturers are free to add generous amounts of sodium to their food. However, use of the term "healthy" should be restricted to foods that truly are healthful.
6. I wonder if many smaller manufacturers have already made the change and would be discriminated against in the marketplace in favor of the petitioner and a few others who have delayed implementing the more restrictive standard.
7. If FDA is planning to implement a labeling requirement more strict than the second tier sodium provision, a delay until January 1, 2004 makes sense so that manufacturers would not have to remake the change when the stricter standards come into play. An additional two-year delay however, until January 1, 2004, seems unnecessary and would harm many, many persons.
8. FDA is to be complimented for allowing the public to comment on this action, when it could have slipped by unnoticed. I thank you for this opportunity to comment.

Yours truly,

A handwritten signature in black ink that reads "Douglas R. Buck". The signature is written in a cursive, flowing style.

Douglas R. Buck, PhD  
Nutrition consultant

STATE OF CONNECTICUT  
DEPT. OF SOCIAL SERVICES  
ELDERLY SERVICES DIVISION  
25 SIGOURNEY STREET  
HARTFORD, CT 06106



Dockets Management Branch (HFA-305)  
Food and Drug Administration, Rm. 1061  
5630 Fishers Lane  
Rockville, MD 20857